

## REMARKS

### Claim Rejections – 35 USC §§102 and 103

Claims 1-20, 28, 29, 33-42, 44-46 and 48-60 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,059,193 to Kuslich, and claims 21, 43 and 47 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kuslich, and claims 22-27 have been rejected as being unpatentable over Kuslich in view of U.S. Patent No. 6,371,989 to Chauvin.

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Independent claims 1, 33, 37 and 45 each recite that the expansion member is engaged with the first and second axial walls at a location intermediate the end portions/end walls of the implant “and extending transversely between and engaging central portions of said first and second axial walls” to provide expansion/outward deformation along the transverse axis. Independent claim 50 similarly recites that the intervertebral implant is expanded by engaging the expansion member with the first and second axial walls at a location intermediate the first and second transverse end walls, with the expansion member “extending transversely between and engaging mid-portions of the first and second axial walls” to engage the first and second axial walls against vertebral bodies.

The grounds for the rejection of pending independent claims 1, 33, 37, 45 and 50 as being anticipated by Kuslich are set forth in the Office Action as follows:

Kuslich discloses ... a body 12 having axial walls 26 interconnected at their ends and an expansion member 16, 20 co-acting with the walls to expand the body along a transverse axis (see, e.g., Fig. 1).... Fig. 1 clearly shows that the expansion member contains four diametrically opposed (and transversely extending) expansion member portions (e.g., 20) that are intermediate the end portions and that engage central portions of the axial walls 26 to expand the body along a transverse axis. (See pages 2 and 5).

The rejection of pending independent claims 1, 33, 37, 45 and 50 as being anticipated by Kuslich is based, in large part, on the assertion that the inner tubular structure 20 is part of the expander 14. However, Kuslich teaches that the inner tubular structure 20 is part of the implant body 12, and not the expander 14. (Col. 3, l. 30-60). Indeed, Kuslich expressly teaches that the inner tubular structure 20 and the outer tubular structure 22 “are joined into a completed assembly 60, as shown in FIG. 13. Assembly 60 is formed by sliding inner structure 20 into outer structure 22 as shown in FIG. 12. Inner structure 20 is adhered to the inner surface of outer structure 22 through any suitable mean, such as adhesives or the like.” (Col. 5, l. 66 to col. 6, l. 3; emphasis added). In summary, Kuslich discloses that the inner and outer tubular structures 20, 22 are joined together to form an integrated/composite implant body 12. (Col. 4, ll. 59-64). Accordingly, the Applicant submits that the assertion set forth in the Office Action that the inner tubular structure 20 is part of the expander 14 (which constitutes the primary basis for rejection of each of the pending independent claims) is incorrect.

Furthermore, the Applicant maintains that the implant expander 14 of Kuslich does not engage central portions of the axial walls of the implant body 12. Instead, the implant expander 14 includes end caps 18, 32 that engage the end rings 23 of the implant body 12, and which are drawn together to exert an axial compressive force onto the end rings 23 to expand the implant body 12. Indeed, no portion of the expander 14 is in any way engaged with the axially-extending ribs of the implant body 12 at a location intermediate the end rings 23. Likewise, no portion of the expander 14 in any way extends transversely between and engages central portions/mid- portions of the axially-extending ribs to expand the implant body 12. This is clearly illustrated in Figures 2, 2B and 24 of Kuslich. Moreover, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, the axially-extending ribs 28 do not extend transversely between central portions of the axially-extending ribs 26 of the outer tubular structure 22. Instead, the inner ribs 28 are joined securely to and extend axially along the outer ribs 26, and do not extend transversely between central portions of the outer ribs 26.

For at least the reasons set forth above, the Applicant submits that each of the independent claims 1, 33, 37, 45 and 50 are not anticipated by Kuslich. Nevertheless, in order to advance prosecution of the subject application, the Applicant has amended each of the

independent claims 1, 33, 37, 45 and 50 to improve their form.

Specifically, independent claims 1, 37 and 45 have been amended to further recite “said expansion member comprising an internal support member positioned within a central region of said inner chamber and having a height extending transversely between and engaging opposing inner surfaces of said central portions of said first and second axial walls”. Support for this amendment is found, for example, at paragraphs 45 and 56 and Figures 1, 5 and 7 of the published version of the subject application. (See U.S. Patent Application Publication No. 2005/0131536).

As shown most clearly in Figures 2, 2B and 23 of Kuslich, the implant 10 does not include any structure or element that could be construed as an internal support member positioned within a central region of the interior of the implant body 12 and having a height extending transversely between and engaging opposing inner surfaces of central portions of the axially-extending ribs 26, 28. Indeed, the only structure positioned within the central region of the interior of the implant body 12 is the tie rod 16 of the expander 14. However, the tie rod 16 does not have a height that extends transversely between and engages opposing inner surfaces of the central portions of the axially-extending ribs 26, 28. Furthermore, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, the axially-extending ribs 28 likewise do not constitute an internal support member having a height that extends transversely between and engages opposing inner surfaces of the central portions of the axially-extending ribs 26, 28.

Moreover, providing an internal support member positioned within a central region of the inner chamber of the implant body which has a height extending transversely between and engaging opposing inner surfaces of central portions of the axial walls not only serves to expand the implant body, but also provides transverse support to the axial walls at a central location of the implant to resist compression loading onto the implant body by the adjacent vertebrae, and to provide structural stability and rigidity to the implant body. Indeed, as set forth in paragraph 56 of the published version of the subject application, “positioning of the expansion pin 24 within the center compartment 90c of the inner chamber 40 provides additional support and rigidity to the upper and lower walls 30, 32 of the fusion cage 22 to resist compression loads from the vertebral bodies  $V_U$ ,  $V_L$ , particularly near the central portion 22c of the fusion cage 22 which is

otherwise devoid of internal support members.” However, the Kuslich implant fails to provide any type of transverse support member at a central region of the implant interior that is engaged between central portions of the axially-extending ribs 26, but instead relies solely on the axial compressive force exerted onto the end rings 23 of the implant body 12 to expand the implant body and to resist vertebral loading.

Accordingly, further reasons exist as to why independent claims 1, 37 and 45 are not anticipated by Kuslich. Therefore, withdrawal of the rejection of the independent claims 1, 37 and 45 and allowance of the same is respectfully requested.

Additionally, in order to advance prosecution of the subject application, the Applicant has amended independent claim 33 to further recite “said axial walls and said transverse end walls defining generally flat and planar upper and lower vertebral bearing surfaces extending substantially entirely across said implant width”. Support for this amendment is found, for example, at paragraphs 27 and 54 and Figures 1, 2 and 4 of the published version of the subject application. With regard to Kuslich, the implant body 12 clearly does not include “generally flat and planar upper and lower bearing surfaces” that extend substantially entirely across the width of the implant body 12. To the contrary, the implant body 12 has a cylindrical configuration, and the outer surfaces defined by the end rings 23 and the axially-extending ribs 26 of the implant body 12 are each circular, and clearly do not define “generally flat and planar upper and lower vertebral bearing surfaces” that extend “substantially entirely across” the width of the implant body 12. Accordingly, further reasons exist as to why independent claim 33 is not anticipated by Kuslich. Therefore, withdrawal of the rejection of the independent claim 33 and allowance of the same is respectfully requested.

Furthermore, in order to advance prosecution of the subject application, the Applicant has amended independent claim 50 to further recite “expanding the intervertebral implant along the transverse axis by slidably engaging the expansion member along opposing inner surfaces of the first and second axial walls in a direction along the longitudinal axis to a location intermediate the first and second transverse end walls with the expansion member extending transversely between and engaging mid-portions of the first and second axial walls”. Support for this amendment is found, for example, at paragraph 43 and Figures 1, 6 and 7 of the published version of the subject application. With regard to Kuslich, the implant body 12 is not expanded

by “slidably engaging” any portion of the expander 14 (including the tie rod 16 and the end caps 18 and 32) “along opposing inner surfaces” of the axially-extending ribs 26, 28 in an axial direction. Furthermore, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, as indicated above, Kuslich specifically discloses that the inner and outer tubular structures 20, 22 are joined together to form the integrated/composite implant body 12. Accordingly, no portion of the inner tubular structure 20 is slidably engaged along opposing inner surfaces of the axially-extending ribs 26 of the outer tubular structure 22 to expand the implant body 12. Accordingly, further reasons exist as to why independent claim 50 is not anticipated by Kuslich. Therefore, withdrawal of the rejection of the independent claim 50 and allowance of the same is respectfully requested.

Dependent claims 2-29, 34-36, 38-44, 46-49 and 51-60 depend either directly or indirectly from independent claims 1, 33, 37, 45 and 50, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of their respective independent base claims. However, further reasons exist in support of the patentability of the dependent claims.

For example, dependent claims 9, 29, 34 and 40 have been amended to recite that “said expansion member slidably engaged along opposing inner surfaces of said first and second axial walls during said axial displacement”. However, as indicated above with regard to independent claim 50, no portion of the expander 14 (including the tie rod 16 and the end caps 18 and 32) is slidably engaged along opposing inner surfaces of the axially-extending ribs 26, 28 to expand the implant body 12 along a transverse axis. Furthermore, even assuming arguendo that the axially-extending ribs 28 of the inner tubular structure 20 could somehow be construed to constitute a portion of the expander 14, as indicated above, Kuslich specifically discloses that the inner and outer tubular structures 20, 22 are joined together to form the integrated/composite implant body 12. Accordingly, no portion of the inner tubular structure 20 is slidably engaged along opposing inner surfaces of the axially-extending ribs 26 of the outer tubular structure 22 to expand the implant body 12 along a transverse axis.

Additionally, dependent claims 8 and 41 have been amended to recite that the expansion member cooperates with the first and second axial walls to “uni-axially expand said body along

said transverse axis”. Similarly, claim 48 has been amended to recite that “expansion of said body comprises outward deformation and uni-axial expansion of said first and second axial walls along said transverse axis”, and claim 53 has been amended to recite “wherein moving the expansion member within the central portion of the inner chamber results in uni-axial expansion of the first and second axial walls along the transverse axis”. Figures 6 and 7 clearly illustrate the expansion member 24 cooperating with the axial walls 30, 32 to uni-axially expand the implant body 22 along the transverse axis T. With regard to Kuslich, as should be readily apparent, the implant body 12 is expanded along multiple axes to provide a spherical-shaped expanded implant configuration (see Figure 1), and therefore does not uni-axially expand along a single transverse axis.

Furthermore, dependent claim 35 has been amended to recite that “said expansion member comprises an internal support member positioned within a central region of said inner chamber and having a height extending transversely between and engaging opposing inner surfaces of said central portions of said first and second axial walls”, and dependent claim 52 has been amended to recite that “the expansion member comprises an internal support member positioned within a central region of the inner chamber and having a height extending transversely between and engaging the opposing inner surfaces of the mid-portions of the first and second axial walls”. As indicated above with regard to independent claims 1, 37 and 45, Kuslich fails to disclose these features.

The Applicant notes that dependent claims 7, 13, 14, 17, 19, 20 and 39 have been amended to improve their form and to conform to the antecedent basis established in their respective independent base claims and/or intervening claims.

### CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 1-29 and 33-60. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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